

REPRODUCED BY
ART 34 AMDT

Claims

1. A process for the preparation of transplant acceptance inducing cells of monocytic origin characterised in that
- 5
- a) monocytes are isolated from blood;
- b) the monocytes are multiplied in a suitable culture medium which contains the cellular growth factor M-CSF;
- 10
- c) the monocytes are cultivated simultaneously with or following step b) in a culture medium containing γ -IFN; and
- 15
- d) the transplant acceptance inducing cells formed in step c) are obtained by separating the cells from the culture medium.
- 20
2. A process according to claim 1 characterised in that the monocytes are of human origin.
3. A process according to claims 1 or 2 characterised in that the monocytes are isolated from the blood in such a manner that next to the monocytes also lymphocytes are
- 25
- present in an amount of at least 10% by reference to the total cell number in the isolate.
4. A process according to claims 1 to 3, characterised in that the transplant acceptance inducing cells formed in
- 30
- step c) or obtained in step d) are selected by binding to the antibody produced by the hybridoma cell line DSM ACC2542.

5. A process according to claims 1 to 4, characterised in that among the transplant acceptance inducing cells formed in step c) or obtained in step d) of claim 1 or obtained in the selection step according to claim 4 those cells are selected which co-express the antigens CD3 and CD14 on their cell surface.
6. A process according to claims 1 to 5, characterised in that the M-CSF concentration in the culture medium is 1 to 20 µg/l.
7. A process according to claims 1 to 6, characterised in that, subsequent to step b) the monocytes are cultivated for 24 to 72 hours in a culture medium containing γ-IFN, the cultivation in the presence of γ-IFN beginning 3 to 6 days after the beginning of cultivation step b).
8. A process according to claim 7, characterised in that the γ-IFN concentration in the culture medium is 0.1 to 20 ng/ml.
9. A process according to claims 1 to 8 characterised in that the total cultivation period in steps b) and c) is 4 to 8 days.
10. A process according to claims 1 to 8 characterised in that subsequent to step d) of claim 1, or subsequent to the selection steps according to claims 4 and 5, the cells are suspended in a suitable cell culture medium or in a PBS or NaCl solution.
11. A process according to claims 1 to 10 characterised in that the cells are suspended in a freezing medium and are subsequently deep frozen.

12. A process according to claim 11 characterised in that the freezing medium comprises fetal calf serum (FCS) or human AB serum and DMSO.
- 5
13. Transplant acceptance inducing cells of monocytic origin obtainable by any of the processes according to claims 1 to 12.
- 10 14. Transplant acceptance inducing cells according to claim 13 characterised in that they co-express the antigens CD3 and CD14 on their cell surface.
- 15 15. Transplant acceptance inducing cells according to claims 13 or 14 characterised in that they are of human origin.
16. Cell preparation containing the transplant acceptance inducing cells according to claims 13 to 15 in a suitable medium.
- 20
17. Pharmaceutical composition containing transplant inducing cells of monocytic origin.
- 25 18. Pharmaceutical composition containing the transplant acceptance inducing cells according to claims 13 to 15 or the cell preparation according to claim 16..
- 30 19. Use of the transplant acceptance inducing cells according to claims 13 to 15 or the cell preparation according to claim 16 for manufacturing a pharmaceutical composition for the suppression of transplant rejection reactions.

20. The use of transplant acceptance inducing cells according to claims 13 to 15 or the cell preparation of claim 16 for *in vitro* generating and/or propagating regulatory T-lymphocytes.

21. The use according to claim 20, wherein the regulatory T-lymphocytes co-express the antigens CD4 and CD25 on their cell surface.

22. A process for the generation and/or propagation of regulatory T-lymphocytes, characterised in that

a) transplant acceptance inducing cells according to claims 13 to 15 or a cell preparation according to claim 16 are co-cultivated with a T-lymphocyte preparation, and

b) the regulatory T-lymphocytes are optionally obtained from the culture medium.

23. A process according to claim 22, characterised in that the regulatory T-lymphocytes co-express the antigens CD4 and CD25 on their cell surface.

24. A process according to claims 22 or 23, characterised in the regulatory T-lymphocytes are obtained from the culture medium by FACS sorting.

25. Regulatory T-lymphocytes obtainable by the process of claims 22 to 24.

26. Hybridoma cell line DSM ACC2542.

27. Antibodies produced by the hybridoma cell line DSM
ACC2542.
- 5 28. The use of the antibody according to claim 22 for the de-
tection and/or selection of transplant acceptance induc-
ing cells.